PATENTS Atty. Docket No.: 36119.232US3/AM101272US
Appl. No.: 10/553,139 Response to Office Action

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in this application.

Listing of claims:

- 1. (Previously Presented) A pharmaceutical composition useful for the treatment or control of bacterial infections by parenteral administration, the composition comprising effective amounts of (a) piperacillin or a pharmaceutically acceptable salt thereof, (b) tazobactam or a pharmaceutically acceptable salt thereof; and (c) an aminocarboxylic acid chelating agent or a pharmaceutically acceptable salt thereof, wherein the aminocarboxylic acid chelating agent is at least one compound selected from the group consisting of O,O'-bis(2-aminoethyl)ethyleneglycol-N,N,N',N'-tetraacetic acid (EGTA) and trans-1,2-diaminocyclohexane-N,N,N',N'-tetraacetic acid (CyDTA).
- (Original) A pharmaceutical composition according to claim 1 further comprising a buffer adapted to maintain a pH within the range of 6.0 to 7.5.
- (Original) A pharmaceutical composition according to claim 2 wherein the buffer is adapted to maintain a pH of substantially 6.5.
- (Original) A pharmaceutical composition according to claim 2 wherein the buffer is citrate.
- (Original) A pharmaceutical composition according to claim 1 containing piperacillin sodium, tazobactam sodium and a sodium salt of the aminocarboxylic acid chelating agent.
- (Original) A pharmaceutical composition according to claim 5 further comprising sodium citrate as buffer.
- 7-37. (Cancelled)
- (Currently Amended) A pharmaceutical composition according to claim 1 further comprising an aminoglycoside selected from amikacin.
- 39. (Cancelled)
- (Currently Amended) A pharmaceutical composition according to claim 6 further comprising an aminoglycoside <u>selected from amikacin</u>.

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- 41. (Cancelled)
- 42. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the composition is in the form of a powder that can be reconstituted by addition of a compatible reconstitution diluent prior to parenteral administration.
- 43. (Previously Presented) A pharmaceutical composition according to claim 6, wherein the composition is in the form of a powder that can be reconstituted by addition of a compatible reconstitution diluent prior to parenteral administration.
- 44. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the composition is in the form of a frozen composition adapted to be thawed and, if desired, diluted with a compatible diluent prior to parenteral administration.
- 45. (Previously Presented) A pharmaceutical composition according to claim 6, wherein the composition is in the form of a frozen composition adapted to be thawed and, if desired, diluted with a compatible diluent prior to parenteral administration.
- 46. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the composition is in a form ready to use for parenteral administration.
- 47. (Previously Presented) A pharmaceutical composition according to claim 6, wherein the composition is in a form ready to use for parenteral administration.
- 48. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the composition is in the form of a solution and the piperacillin is present in an amount from about 8 mg/ml to about 500 mg/ml.
- 49. (Previously Presented) A pharmaceutical composition according to claim 6, wherein the composition is in the form of a solution and the piperacillin is present in an amount from about 8 mg/ml to about 500 mg/ml.
- 50. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the composition is in the form of a solution and the tazobactam is present in an amount from about 0.1 mg/ml to about 125 mg/ml.
- (Previously Presented) A pharmaceutical composition according to claim 6, wherein
 the composition is in the form of a solution and the tazobactam is present in an
 amount from about 0.1 mg/ml to about 125 mg/ml.

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- 52. (Previously Presented) A pharmaceutical composition of claim 6, wherein the composition is in the form of a solution and the citrate buffer is present in an amount from about 0.25 mg/ml to about 25 mg/ml.
- 53. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the composition is in the form of a solution, said composition further comprising an effective amount of dextrose to render the composition physiologically isosmotic.
- (Previously Presented) A pharmaceutical composition according to claim 53, wherein the effective amount of dextrose is from about 5 mg/ml to about 100 mg/ml.
- 55. (Currently Amended) A pharmaceutical composition according to claim 40 41, wherein the composition is in the form of a solution and the amikacin is present in an amount from about 0.1 mg/ml to about 75 mg/ml.
- 56. (Cancelled)
- 57. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the composition is in the form of a solution, and wherein the aminocarboxylic acid chelating agent is present in an amount of about 0.002 mg/ml to about 10 mg/ml.
- 58. (Previously Presented) A pharmaceutical composition according to claim 57, wherein the aminocarboxylic acid chelating agent is present in an amount of about 0.003 mg/ml to about 1 mg/ml.
- 59. (Previously Presented) A pharmaceutical composition according to claim 1, wherein said pharmaceutical composition is a dose concentrate in a sealed container wherein said container has a space sufficient for introduction of a volume of aqueous solvent sufficient to form a concentrated solution of said pharmaceutical composition.
- 60. (Previously Presented) A pharmaceutical composition according to claim 6, wherein said pharmaceutical composition is a dose concentrate in a sealed container wherein said container has a space sufficient for introduction of a volume of aqueous solvent sufficient to form a concentrated solution of said pharmaceutical composition.
- 61. (Previously Presented) A pharmaceutical composition according to claim 1, wherein said pharmaceutical composition is in the form of a solution and is a unit dose contained in an IV bag or IV bottle for intravenous administration.

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62. (Previously Presented) A process for the manufacture of a reconstitutable pharmaceutical composition in the form of a powder which process comprises the steps of:

- (a) dissolving effective amounts of piperacillin or a pharmaceutically acceptable salt thereof, tazobactam or a pharmaceutically acceptable salt thereof, and an aminocarboxylic acid chelating agent or a pharmaceutically acceptable salt thereof in an aqueous solvent to form a solution, wherein the aminocarboxylic acid chelating agent is at least one compound selected from the group consisting of O,O'-bis(2-aminoethyl)ethyleneglycol-N,N,N',N'-tetraacetic acid (EGTA) and trans-1,2-diaminocyclohexane-N,N,N',N'-tetraacetic acid (CyDTA);
- (b) adjusting the pH of said solution in the range of about 6.0 to about 7.5; and
- (c) freeze drying said solution to form a reconstitutable powder.
- 63. (Currently Amended) The process according to claim 62 further comprising in step (a) dissolving an aminoglycoside <u>selected from amikacin</u> with said piperacillin, tazobactam and aminocarboxylic acid chelating agent.
- 64. (Cancelled)
- (Currently Amended) The process according to claim 63 64, wherein the aminoglycoside is amikacin and is present in an amount of about 0.1 mg/mL to about 75 mg/mL.
- 66. (Cancelled)
- 67. (Previously Presented) The process according to claim 62 further comprising in step (b) the pH is adjusted to about 6.5 with an effective amount of a buffer.
- (Previously Presented) The process according to claim 67, wherein the buffer is citrate.
- (Previously Presented) The process according to claim 67, wherein the buffer is sodium citrate
- 70. (Previously Presented) A method for the treatment or control of bacterial infections in a mammal, said infections being caused by piperacillin/tazobactam susceptible bacteria wherein the method comprises parenteral administration of a therapeutically effective amount of the pharmaceutical composition of claim 1 to said mammal.

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- 71. (Previously Presented) A method for the treatment or control of bacterial infections in a mammal, said infections being caused by piperacillin/tazobactam susceptible bacteria wherein the method comprises parenteral administration of a therapeutically effective amount of the pharmaceutical composition of claim 6 to said mammal.
- 72. (Currently Amended) A method for the treatment or control of bacterial infections in a mammal, said infections being caused by piperacillin/tazobactam susceptible bacteria wherein the method comprises parenteral co-administration of a therapeutically effective amount of the pharmaceutical composition of claim 1 and an aminoglycoside selected from amikacin to said mammal.
- 73. (Currently Amended) A method for the treatment or control of bacterial infections in a mammal, said infections being caused by piperacillin/tazobactam susceptible bacteria wherein the method comprises parenteral co-administration of a therapeutically effective amount of the pharmaceutical composition of claim 6 and an aminoglycoside selected from amikacin to said mammal.
- 74. (Cancelled)
- 75. (Cancelled)